unobserved selectivity, a condition not satisfied in many retrospective healthcare studies, especially those based on administrative claims databases.

PMD5

IMPROVING REPORTS OF PRO DATA TO SUPPORT AN EFFECTIVENESS CLAIM

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OBJECTIVES: The same standards should apply for measuring patient reported outcomes (PRO) as for any clinical measure used for an effectiveness claim. Yet, discrepancies between the number of submissions and the number of PRO claims granted illustrate how difficult it is to demonstrate the "substantial evidence" required by authorities. Reporting PRO data separately from the clinical data makes reviewing PRO claims difficult. However, International Conference Harmonization (ICH) guidelines provide no standard location for PRO measurement information. Better integration of PRO data in clinical reports and standardized documentation of PRO measures would improve the reviewing process and enhance the likelihood of securing claims. We will present the value of implementing a standardized approach to documenting PRO measures in regulatory submission reports. **METHODS:** Our recommendations are based on ICH guidelines and the ERIQA and PRO Harmonization group recommendations. While current ICH report guidelines provide no headings for documenting background information on PRO measures, appropriate headings can be added to report PRO methods and findings as part of the primary clinical trial report without modifying the ICH numbering system. However, the questionnaire development and validation relevant to the condition and treatment considered are better located in supporting appendices as are reviews of literature documenting the use and interpretation of data collected with it. **RESULTS:** These appendices should include evidence of the clinical significance of differences to help reviewers familiarize themselves with the instrument. **CONCLUSION:** Better integration of PRO in clinical study report guidelines and the development of a specific system for standardized documentation of PRO measures will enhance transparency and acceptance of PRO data, and thereby increase the acceptance by decision-makers of effectiveness claims based on PRO.

PMD6

ESTIMATING THE TRAJECTORY-ADJUSTED IMPACT OF ACUTE EVENTS ON PATIENT-REPORTED OUTCOMES

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OBJECTIVES: To establish clinical meaningfulness of effect sizes and validate measures of patient-reported outcomes (PROs), it is important to understand the effect of acute clinical events on PROs. When PROs are measured before and after an acute event, there are several options for measuring change. This example illustrates the benefit of adjusting estimates of change for patients' pre-event trajectories. **METHODS:** To determine the effect of pathologic fractures (PF) on PROs, we used data from a clinical trial of zoledronic acid versus placebo in patients with prostate cancer (N = 643). Only patients who experienced a PF were included in this analysis (n = 76). For illustrative purposes, the Functional Assessment of Cancer Therapy-General (FACT-G) total score was compared before and after each patient's first PF using two methods: 1) estimate simple mean change from pre-PF value to post-PF value and perform a paired t-test; and 2) use a linear mixed effects model to analyze all time points from baseline to the first time point after the PF, with a dummy variable indicating the pre-PF (0) and post-PF (1) status. The fixed-effect for the dummy variable is the trajectory-adjusted mean change (TAMC). (Note: analyses not reported here showed significant effects of PF on three of the four FACT subscales). **RESULTS:** The simple mean change was –4.03 (SD = 13.57), which was significant by a paired t-test (p = 0.04). The TAMC, however, was –2.00 (95% CI = –5.53, 1.52), and was not statistically significant (p = 0.26). **CONCLUSIONS:** In assessing the impact of acute events on PROs, simple pre-post comparisons may misestimate effect size and/or statistical significance. The mixed-effects model presented here more accurately assesses changes in PROs by adjusting for the pre-event trajectory due to prostate cancer with bone metastases, isolating the change in PROs attributable to the acute clinical event.

PMD7

THE CONGRUENCE OF SELF-REPORT WITH OTHER MEASURES OF MEDICATION ADHERENCE: A SUMMARY OF THE LITERATURE

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OBJECTIVES: The objective of this paper is to determine the congruence of self-report measures of medication adherence with other measures of adherence. **METHODS:** A literature search was conducted across 1978–2002. MEDLINE, PsychInfo, IPA and ISI databases were used to identify studies that met the following inclusion criteria: 1) study included at least one self-report measure and one non-self-report measure of adherence; 2) data were reported that would allow a comparison of the measures (e.g., individual scores or a correlation/concordance statistic); and 3) the report was in English. The studies were categorized by type of self-report adherence measure (questionnaire, diary, interview) and by type of non-self-report method (administrative claims, pill count/canister weight, biological assay, electronic mea-

sures, or third-party opinion). The congruence of the adherence measures was classified as high, medium or low. This allowed a comparison of the congruence between categories of adherence measures. **RESULTS:** Eighty-four studies were identified that met the inclusion criteria. The distribution of self-report measures were: interview (n = 48), questionnaire (n = 22), diary (n = 14). The non-self-report methods were: electronic measures (n = 29), pill count/canister weight (n = 22), biological assays (n = 17), claims (n = 10) and third-party opinion (n = 6). There was substantial variation in the pattern of congruence across the different types of self-report measures. Interviews had the poorest congruence with other measures of adherence (only 15 of 48 comparisons found high congruence). Diaries and Questionnaires were more likely to exhibit high congruence with other measures (10 of 14 studies, and 12 of 22 studies, respectively). Only 5 of the 29 studies involving electronic measures reported high congruence with self-reports, although the other non-self-report measures were often highly congruent with self-report (32 of 53 studies). **CONCLUSION:** The congruence of self-report and other measures of medication adherence varies widely based upon the type of measure.

PMD8

PATIENT SAFETY RESEARCH: A DISCUSSION OF TERMINOLOGY, PROPOSED DEFINITIONS, AND A CONCEPTUAL MODEL FOR ADVERSE EVENTS INVOLVING MEDICAL DEVICES

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Terminology and conceptual causation models in patient safety research arose separately in the fields of human factors, epidemiology, engineering risk management, and drug safety; they are confusing and conflict with one another. Much of the terminology perpetuates undesirable concepts, such as implicit determination of causation, and poorly fits an important arena, safety of medical devices. **OBJECTIVES:** To review and propose terminology and to propose a conceptual model for interpreting research and designing interventions to reduce confusion and enhance understanding and communication in this area. **METHODS:** We systematically reviewed the terminology used in scientific literature, discussed the meanings, and made proposals. We also reviewed existing models and proposed one that enhances the models that are in the literature. **RESULTS:** We propose a set of terms and definitions for "error," "hazard," "adverse event," "preventable adverse event," "potential adverse event," and "risk." The terms and their definitions are as neutral as possible with respect to "blame issues" such as "responsibility," "negligence," and "intentionality." We also proposed a model that builds on these ideas and on Rothman's "causal pie" concept. The concepts allow explicit recognition of partial, rather than full, understanding of hazardous situations. **CONCLUSIONS:** The proposed terms, definitions, and model could clarify thought, research design and interpretation, the process of designing and evaluating patient safety interventions, and communication between interested parties, including researchers, laypersons, healthcare providers, and risk managers.

PMD9

INTERNET-BASED PATIENT REGISTRIES IN COMMUNITY PRACTICE

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OBJECTIVES: To assess the level of user acceptance for an Internet-based methodology for collecting patient outcomes data from an observational multi-site postmarket study gathering data from community based ophthalmic practices. **METHODS:** The study coordinator at each participating site (N = 41) was issued an ID & Password for logging onto the secure and confidential site. Training of the study coordinators on how to use the site and patient confidentiality considerations took about 30 minutes. Two sets of questions were being asked: Physician Questions (8 baseline, 4 followup) and Patient Questions (9 baseline, 18 followup). Patients were followed for approximately six months. A small honorarium in return for completing the study documents was paid. Both glaucoma specific clinical & QOL data was collected and analyzed. **RESULTS:** Forty-one sites registered 360 patients for the study. Final follow-up data was entered on 318 of the 360 registered patients (88%) using the web-based case report forms. Eighty-seven percent (36/41) responded to a user survey and all respondents 100% (36/36) felt the system was simple and east to use. Several users were so enthusiastic they gave text quotes of additional positive praise on the survey. Many indicated they actually enjoyed participating. **CONCLUSIONS:** Internet-based post-market studies are a promising methodology for the benefit of both the study sponsor and participating sites.

PMD10

EVALUATING RETROSPECTIVE STUDY POSTERS PRESENTED AT THE ISPOR 7TH ANNUAL CONFERENCE

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OBJECTIVE: Evaluate the quality of retrospective study design posters presented at the ISPOR Seventh Annual Meeting using the criteria published by the ISPOR Task Force on Retrospective Databases. **METHODS:** Of the 337 posters presented at the conference, we had access to 133 (39%) from on site collection or the ISPOR website. These 133 posters were categorized into one of 5 cate-